

gets started reviewing a cancer drug submitted to the agency in April would be laid off on October 1, before the reviewer is able to finish his or her work. The sooner we reauthorize the agreements, the better—to give patients, reviewers, and companies certainty.

In addition to harming patients and families that rely on medical innovation, a delay in reauthorizing the user fees would threaten biomedical industry jobs and America's global leadership in biomedical innovation.

#### PROCESS FOR REAUTHORIZATION

I am hopeful that this committee, and this Congress, can work in a bipartisan manner to reauthorize the user fees before the August recess.

Congress must pass legislation reauthorizing and updating the fees to support the recommendations contained in what are called "commitment letters" sent to Congress in January.

Now these commitment letters are part of the agreements between FDA and industry—they establish the agency's commitments, such as timelines for application review or to put out guidances in exchange for the fees Congress authorizes. The letters were transmitted to Congress in January of this year.

So today's hearing is not the first time members of Congress or the public is hearing about the recommendations for reauthorization.

In Congress, while we were working on the 21st Century Cures and after it was signed into law, the HELP Committee had 15 bipartisan briefings, some of which were in conjunction with the Energy and Commerce Committee in the House of Representatives as well, so we could hear from FDA and industry about the reauthorization. The first of those briefings was back in late 2015.

Outside of Congress, the FDA posted meeting minutes after every negotiation, and held public meetings to hear feedback.

So the content of the commitment letters, and the changes to the fee authorizations, should not be new, or a surprise, for any member of this committee.

After the April 4th hearing, I hope to move to mark-up the legislation in committee as soon as possible.

This is the first time that the user fees have sunset in the first year of a new administration, so we are starting hearings a little later this year than we did in 2012.

In order to get this done on time, any additional policies that Senators may want to attach need to be broadly bipartisan, related to human medical products, and non-controversial in order to avoid slowing the package down.

#### HOW REAUTHORIZATION BUILDS ON 21ST CENTURY CURES

There are many improvements in the commitment letters and fee structure in these reauthorizations to be excited about.

The prescription drug and medical device reauthorizations include many provisions that build on the work of 21st Century Cures, such as: involving patients in drug and medical device development, dedicated staff to assist in the development and review of rare disease drugs, improved timelines, increased guidance for drug and device combination products, and modernizing the clinical trial process.

There are important structural reforms. Each agreement contains reporting measures built both by FDA and by independent third parties, so we can see how the changes are working. FDA is going to work to implement full time reporting by 2022, so Congress, patients, and medical product manufacturers will have a better picture about how resources are being used at FDA and understand what is needed to do what we ask.

The biosimilar and generic drug user fee agreement includes additional staff and resources to approve more biosimilars and more generic drugs, which provide more competition and lower drug costs.

These are just a few of the highlights of the reauthorization and commitment letters. It is a good agreement for patients, and I look forward to working with Senator Murray and all the members of the Committee to get it done expeditiously.

#### TRIBUTE TO NINA M. SERAFINO

Mr. CARDIN. Mr. President, I would like to take this opportunity to extend my appreciation to a dedicated public servant at the Congressional Research Service, CRS, of the Library of Congress, Ms. Nina M. Serafino. Ms. Serafino recently retired after more than 35 years of service to Congress. This length of public service is not only a credit to Ms. Serafino, but also a demonstration of the dedication that she and many other CRS employees bring to support our work here in Congress.

During Ms. Serafino's 35 years with CRS, she provided Congress with many types of assistance to help inform national policymaking on a variety of war and peace issues. From 1981, when she joined CRS, through the 1980s, she was deeply involved in bipartisan efforts to evaluate U.S. policy in Central America. Her work focused on providing a common understanding of the problems and possibilities in the region in order to shape U.S. options and alternatives. Particularly noteworthy was her original research on aspects of the Central American conflicts where there was a little or no information available from other sources. Responding to a congressional request, she conducted field research and delved into the Library of Congress's historical materials to provide a unique report on the many parties of the civic opposition to the Sandinista government in Nicaragua. Similarly, her field research on the Latin American "Contadora" effort significantly informed congressional deliberations regarding the peace process to end the conflicts in Nicaragua and El Salvador.

With the advent of U.S. military involvement in peacekeeping operations in the Balkans and elsewhere beginning in the 1990s, Ms. Serafino contributed to congressional efforts to comprehend the plethora of institutional and budgetary considerations relevant to our government's ability to bring its full toolbox to bear in those operations. Providing information and analysis through reports, briefings, and several comprehensive conferences and workshops for Members and staff, Ms. Serafino assisted Congress in understanding the possibilities, constraints, and options for legislating and overseeing military and civilian tools and the development of interagency resources and mechanisms.

As Congress sought to comprehend and deal with the post-9/11 world, Ms. Serafino supplemented targeted CRS

work on Afghanistan and Iraq with conferences and reports that brought an historical perspective to congressional deliberations. The conferences and reports provided insights on a wide variety of international experiences in dealing with terrorism and contained historical information and pertinent analysis on previous U.S. interventions and occupations.

Over the past decade, Ms. Serafino also developed a number of products on security assistance and cooperation. Most recently, as the U.S. Government has expanded U.S. military efforts to build partner capacity among foreign security forces worldwide, Ms. Serafino contributed an historical perspective on U.S. security assistance and cooperation development in the post-World War II period to inform our deliberations on an evolving legislative framework for such assistance. Her written work on post-9/11 topics has enlightened both Congress and the broader foreign policy and defense communities.

Throughout Ms. Serafino's career, she won the respect and admiration of her colleagues for her geniality and expertise on Latin America and international security affairs. She won a Distinguished Service Award and several Merit Service and Special Achievement awards. Her steadfast dedication to serve Congress and her commitment to the highest standards of research made a lasting contribution to congressional policy discourse. I have said many times that the Federal workforce is a critical national asset. Ms. Serafino and the other talented and dedicated public servants at CRS are yet another example. While we will miss her contributions, I know my colleagues will want to join me in sending our best wishes to Ms. Serafino for a happy retirement.

#### ADDITIONAL STATEMENTS

##### TRIBUTE TO STEVE HAMMOND

● Mr. CARDIN. Mr. President, today I wish to recognize the three decades of distinguished service journalist Steve Hammond has provided to the citizens of Maryland's Eastern Shore and the viewers of WBOC-TV 16 in Salisbury, MD, "Delmarva's News Leader."

Steve Hammond is a Maryland native, raised in Towson's Rodgers Forge neighborhood. He learned many of life's lessons on the football and lacrosse fields before graduating from the University of Delaware with a degree in mass communications. Since his mother, sister, and brother have all been involved in television production, it is no surprise, perhaps, that Steve gravitated toward the business of broadcasting and interned for several stations. He discovered he felt most at home in the newsroom and was drawn particularly to the variety of daily reporting. In 1985, after working without pay for 2 weeks to illustrate his potential value, Steve was hired by WHYY, a